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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,375	03/14/2001	Shaorong Liu	PB0006	3335

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PATENT DEPARTMENT
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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/808,375	LIU, SHAORONG
	Examiner	Art Unit
	ALEX NOGUEROLA	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 19 is objected to because of the following informality: in line 5 "segments" should be -- segment -- . Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 8, 9, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Simpson et al. (US 6,143,152) ("Simpson").

Addressing claim 8, Simpson discloses a shaped microfabricated capillary array electrophoresis chip (abstract) comprising

a planar substrate having a first major surface defining a plurality of separation channel groups (Figures 4A, 8, and 9),

wherein each separation channel group includes a grouped pair of converging elongate separation channels (channels 670 and 671 in Figure 11 and channels 620 extending from anode 630 and in a separate embodiment the unlabeled channels extending from cathodes 614 and 616 in Figure 8, said channels in Figure 8 converging at a junction region at which channels from wells 602, 604, 606,608,610, and 612 also converge) extending in fluid communication between a common cathode port (674 in Figure 11 and 614 and 616 in Figure 8) and anode port (630 in Figure 8 and 660 in Figure 9) defined by the first major surface (Figures 8 and 9),

wherein each separation channel of the grouped pair of separation channels further includes a loading segment (in Figure 8 the channels that extend from sample ports 604,606,610,612 and in Figure 11 the channels that extend from sample ports 676 and 678),

whereby the first major surface further defines an associated group sample port (ports 604,606,610,612 in Figure 8 and ports 676 and 678 in Figure 11) and a group waste port (ports 602 and 608 in Figure 8 and port 672 in Figure 11) for each separation channel of the grouped pair of separation channels wherein each associated group sample port and group waste port are in fluid communication across the loading segment of a single separation channel (Figures 8 and 11).

Applicant should noted that although Simpson does disclose sample ports, waste ports, a loading segment, separation channels, an anode port, and a cathode port as claimed, the qualifiers before "port"," segment", and "channel," such as "sample", "waste", "separation," "anode," and

"cathode," only indicate intended uses that do not further structurally distinguish the claimed chip, with the exception that "anode" and "cathode" also at least require an electrode in the port.

Addressing claims 9 and 18, as seen in figures 8 and 9 each separation channel group extends in fluid communication from a common anode port.

Addressing claim 17, Simpson discloses a method for forming a shaped capillary array electrophoresis chip (abstract and col. 4, ln. 47 – col. 5, ln. 21) comprising the steps of

providing a substantially planar substrate having a first major surface (col. 4, ll. 47-53),

forming a plurality of separation channel groups in the first major surface (col. 4, ln. 47-col. 5, ln. 21),

wherein each separation channel group includes a grouped pair of converging elongate separation channels (channels 670 and 671 in Figure 11 and channels 620 extending from anode 630 and in a separate embodiment the unlabeled channels extending from cathodes 614 and 616 in Figure 8, said channels in Figure 8 converging at a junction region at which channels from wells 602, 604, 606,608,610, and 612 also converge) extending in fluid communication between a common cathode port (674 in Figure 11 and 614 and 616 in Figure 8) and anode port (630 in Figure 8 and 660 in Figure 9),

wherein each separation channel of the grouped pair of separation channels further includes a loading segment (in Figure 8 the channels that extend from sample ports 604,606,610,612 and in Figure 11 the channels that extend from sample ports 676 and 678),

whereby the first major surface further defines an associated group sample port (ports 604,606,610,612 in Figure 8 and ports 676 and 678 in Figure 11) and a group waste port (ports 602 and 608 in Figure 8 and port 672 in Figure 11) for each separation channel of the grouped pair of separation channels wherein each associated group sample port and group waste port are in fluid communication across the loading segment of a single separation channel (Figures 8 and 11).

Applicant should noted that although Simpson does disclose sample ports, waste ports, a loading segment, separation channels, an anode port, and a cathode port as claimed, the qualifiers before "port"," segment", and "channel," such as "sample", "waste", "separation," "anode," and "cathode," only indicate intended uses that do not further structurally distinguish the claimed chip, with the exception that "anode" and "cathode" also at least require an electrode in the port.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manz (US 5,296,114) ("Manz").

Manz discloses a method for forming a shaped capillary array electrophoresis chip (abstract and col. 7, ll. 57-68) comprising the steps of

providing a substantially planar substrate having a first major surface (Figures 1 and 2 and col. 4, ll. 1-6);

forming *n* converging elongate separation channels in the first major surface (Figure 1 and col. 6, ll. 38-46);

forming a first perimetrical edge segment extending along the first separation channel (note the perimetrical edge parallel to separation channel 4, for example); and

forming a second perimetrical edge segment extending along the last separation channel (note the perimetrical edge parallel to separation channel 8, for example).

Applicant should first note that claim 19 does not require 48 converging elongate separation channels to converge at the same intersection. All the separation channels in Figure 1 of Manz are converging channels in that each channel converges with another channel, although they all do not converge together at the same intersection.

As for having 48 converging separation channels, although the embodiment shown in Figures 1 and 4-8 of Manz only show 4 channels, Manz discloses that the chip may be *n*-sided (col. 6, ll. 38-46), without limiting "n". Indeed, Manz sates that the chip may be circular, which implies a large value for "n". Barring evidence to the contrary, such as unexpected results, the choice of "n", such as n = 48, is just effectively duplicating parts for multiplied effect, which has been held *prima facie* obvious. MPEP 2144.04 VI. B.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (US 6,623,613) ("Mathies") in view of Zanzucchi et al. ("Zanzucchi"). Note that for Mathies the examiner relies upon priority from the provisional applicaoint 60/157,299.

Mathies discloses a method for forming a shaped capillary array electrophoresis chip (abstract and col. 4, ln. 10-36) comprising the steps of

providing a substantially planar substrate having a first major surface (col. 3, ll. 65-67); and

forming a plurality of converging separation channel groups in the first major surface (Figure 4 and col. 6, ln. 64 - col. 7, ln. 30).

Mathies does not disclose forming a first perimetrical edge segment extending along the first separation channel and forming a second perimetrical edge segment extending along the last separation channel.

Zanzucchi discloses a method for forming a shaped capillary array electrophoresis chip having a first perimetrical edge segment extending along a first separation channel and a second perimetrical edge segment extending along the last separation channel in the chip (see module 148 in Figure 7B and the unlabeled module in Figure 10 and col. 6, ll.14-50).

It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the chip shown in Figure 4 of Mathies made of 4 modules (chips) each having a perimetrical edge extending along a first separation channel and a second perimetrical edge extending along a last separation channel as taught by Zanzucchi in the invention of Mathies because then several sets of separations may be performed simultaneously under different conditions. For example, the modules can each be made from a different substrate material (col. 2, ll. 24-27 in Mathies) and wells and channels can be configured in each module so that each module is appropriately suited for a different assay/analysis (col. 2, ll. 20-37 and col. 5, ll. 25-37 in Zanzucchi).

As for having 48 convening channels in each modified, although only 24 coverging channels are shown in each perspective module in Figure 4 of Mathies, clearly this is only exemplary and a larger number of channels, such as 48, could be made in each module. Barring evidence to the contrary, such as unexpected results, having 48 channels in each module, when Mathies shows 24, is just effectively duplicating parts for multiplied effect, which has been held *prima facie* obvious. MPEP 2144.04 VI. B.

8. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
November 1, 2004